

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Zecchino et al.

Serial No.: 09/995,358 Group Art Unit: 1615

Filed: November 26, 2001 Examiner: B. Fubara

For: GELLED AQUEOUS COSMETIC COMPOSITIONS

DECLARATION UNDER 37 CFR 1.132

- I, JAMES T. HARRISON, declare and state as follows:
- 1. I am one of the inventors named in the above-identified application.
- 2. I understand that the Examiner has rejected claims of the application as being obvious in view of the Wheeler (WO 97/32559) reference in view of two other references. It is my understanding that the Examiner has in essence stated that, in view of the combined prior art references, it would have been obvious to substitute a polymeric sulfonic acid for the traditional water soluble gellants disclosed in Wheeler to obtain a composition of the present invention.
- 3. I am familiar with the Wheeler reference. It is my belief that the use of a polymeric sulfonic acid as a gellant of an electrolyte-containing aqueous phase in which an oil-containing biliquid foam is dispersed provides an unexpected advantage over the use of a more

traditional gellant, such as is recommended in Wheeler. In particular, the present inventors have found the compositions of the present invention to maintain stability under conditions that induce instability in the Wheeler compositions.

4. In order to demonstrate the superior stability of the claimed compositions over those of the prior art, I conducted a comparison between a first formula of the type disclosed in Wheeler, namely the toner in Example 5, in which a carbomer type of thickener is used to gel the aqueous phase, and a second formula, differing from the first only in the use of a polymeric sulfonic acid as the gellant, as required by the present claims. The formulas for each composition are attached hereto as Exhibit A. The Wheeler formula will be referred to herein as Formula A, and the formula of the present invention as Formula B.

In each formula, an equivalent amount of gellant (0.08% solids) was used. In addition, to each was added an equivalent amount of NaCl (0.02%) was used to provide the presence of electrolytes in the formula. The final pH of the formulas ranged from about 4.9 (Formula B) to about 5.5 (Formula A), the slight difference being attributable to the different chemical nature of the gellants. However, in each case, pH was below 7, as required by the present claims.

5. Each formula was subjected to a freeze-thaw procedure, which is a standard industry test used to determine the relative stability of a cosmetic formula. In brief, each formula is first frozen for 24 hours at -17°F and then returned to room temperature for 24 hours. This process is then repeated two more times for a total of three times. After the procedure is completed, each formula is observed for signs of instability. At the end of the procedure, Formula A was exhibiting syneresis, i.e., the gel had contracted with a concurrent release of

fluid. In contrast, Formula B retained its integrity after the three freeze-thaw cycles.

- 6. These results demonstrate that products prepared according to the present invention have a greater level of stability than those prepared in accordance with the teachings of the Wheeler reference. In particular, the results demonstrate that the polymeric sulfonic acids of the present invention are superior to the traditional water-soluble gellants, such as the carbomers that are recommended in Wheeler, in their ability to produce a stable gel.
- 7. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

3-18-03

By: // Cll

James T. Harrison

.,

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Zecchino et al.

Serial No.: 09/510,756

Group Art Unit: 1615

Filed: February 22, 2000

Examiner: B. Fubara

For: GELLED AQUEOUS COSMETIC COMPOSITIONS

DECLARATION UNDER 37 CFR 1.132

I_MICHELLE-MATATHIA-JACOBS, declare and state as follows:

- 1. I am one of the inventors named in the above-identified application.
- 2. The experiments described in the specification, and in the present declaration, were conducted by me or a coinventor, or under our direct control and supervision.
- 2. I understand that the Examiner in the subject application has asserted that the application contains no data comparing the claimed polymeric sulfonic acid with other water soluble gellants. In particular, I understand that the Examiner has questioned the criticality of using a polymeric sulfonic acid in gelling a composition containing a biliquid foam dispersed in an salt-containing aqueous phase, where the pH of the composition is less than 7.
- 3. I am familiar with biliquid foams, particularly the biliquid foams disclosed in Wheeler, WO 97/32559, and have worked with several formulations of the type described in the Wheeler document.
- 4. In the course of the development of the present invention; I was asked to formulate a cream product based on a lotion (i.e., water-thin) product formula that contained a biliquid foam component as well as an acid component. To create the cream product, it was necessary to find a way to thicken, or gel, the water phase in which the biliquid foam would be dispersed, to achieve a creamy texture. I began testing a series of formulations which were, in all pertinent aspects, substantially the same as the formulation in Example 1 of the present specification, the variables being the gellant and amounts thereof employed and the acid used being lactobionic acid rather than lactic acid.

- 5. The following gellants (category of gellant, and amounts tested, in parentheses) were tested in the base formula: Carbopol 980 (carbomer, at 10%); Natrosol 250 HHR (hydroxyethylcellulose at 0.25%, 0.5%, 0.75% and 1%); Keltone HVCR NF(algin at 0.5%); Carbopol Ultrez(carbomer at 0.3% and 0.5%); Cellosize Polymer (hydroxyethylcellulose at 0.25%); Kelcosol (algin at 0.5%); Structure SJ (starch, at 6% and 31.24%); Aristoflex AVC(polymeric sulfonic acid, at 1% and 2%).
- 6. Except for the Aristoflex AVC, the polymeric sulfonic acid, none of the gellants tested produced an acceptable product. In all cases, the gellants either failed to produce adequate viscosity, or if a creamlike viscosity was achieved, the resulting product was either lumpy or pilled when rubbed out, and therefore aesthetically and commercially unacceptable.
- 7. Following the guidance provided in Wheeler, using polymers recommended for gelling the biliquid foam containing compositions, I was unable to achieve a satisfactorily thickened product. It was only with the use of the polymeric sulfonic acid that a cream product with acceptable aesthetics was achieved.
- 8. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 8/17/2001

MICHELLE MATATHIA JACO